

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3341. TB-One tablets. U. S. v. 2 Cases * * *. (F. D. C. No. 29786. Sample No. 86304-K.)

LIBEL FILED: October 5, 1950, Southern District of California.

ALLEGED SHIPMENT: On or about September 13, 1950, by the Cosmos Chemical Corp., from New York, N. Y.

PRODUCT: 2 cases, each containing 44 boxes and each box containing 12 50-tablet bottles, of *TB-One tablets* at Los Angeles, Calif.

RESULTS OF INVESTIGATION: This drug was a new drug within the meaning of Section 201 (p) (1) of the law since the name "TB-One," together with the label statement "Caution: To be used only by or on the prescription of a physician," suggested that it was for use in the treatment of tuberculosis in the dosage which had been recommended for the disease in published reports by some physicians, namely 2 to 8 tablets per day for six months or longer; and it was not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under these conditions.

LABEL, IN PART: (Bottle) "TB-One Para Acetylaminobenzal Thiosemicarbazone 25 Mg. Caution: To be used only by or on the prescription of a physician."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: November 27, 1950. Default decree of condemnation and destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

3342. Adulteration and misbranding of Dr. Merrick's Ear Canker Creme. U. S. v. 33 Cartons * * *. (F. D. C. No. 30261. Sample No. 93094-K.)

LIBEL FILED: November 30, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about September 20, 1950, by the Brookfield Laboratories, from Chicago, Ill.

PRODUCT: 33 retail cartons, each containing 1 tube, of *Dr. Merrick's Ear Canker Creme* at Tampa, Fla.

LABEL, IN PART: (Retail carton) "Dr. Merrick's Ear Canker Creme Active Ingredients: Aureomycin, Tyrothricin, 2-Mercaptobenzothiazole, Bismuth Subnitrate, Bismuth Subgallate * * * Net Contents 1/2 Ounce."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess since it contained but an inconsequential trace, if any, of aureomycin.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to the article, which contained but an inconsequential trace, if any, of aureomycin: (Display carton) "contains * * * Aureomycin," (retail carton) "Active Ingredients: Aureomycin," and (leaflet in retail carton) "Aureomycin and Tyrothricin

* * * By combining the two antibiotics we obtain a very desirable synergistic action resulting in more effective curative action than when either Aureomycin or Tyrothricin is used separately."

Further misbranding, Section 502 (1), the article purported to be and was represented as a drug composed in whole or in part of aureomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: January 9, 1951. Default of decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3343. Misbranding of methyltestosterone tablets. U. S. v. Zeno M. Weir (Weir's Drugs & Jewelry). Plea of nolo contendere. Fine, \$150. (F. D. C. No. 29433. Sample Nos. 51383-K, 51388-K, 52645-K.)

INFORMATION FILED: August 30, 1950, Western District of Kentucky, against Zeno M. Weir, trading as Weir's Drugs & Jewelry, Owensboro, Ky.

INTERSTATE SHIPMENT: From the State of New Jersey into the State of Kentucky, of quantities of *methyltestosterone tablets*.

ALLEGED VIOLATION: On or about November 1, 14, and 16, 1949, while the tablets were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a physician's prescription, which acts resulted in the tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged tablets bore no labeling containing directions for use.

DISPOSITION: February 13, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$150.

3344. Misbranding of Nue-Ovo. U. S. v. 24 Units * * * (and 13 other seizure actions.) (F. D. C. Nos. 24663, 24672, 24972, 25050, 25243, 25259, 25272, 25420, 25504, 25516, 26466, 26506, 26538, 26564, 26854. Sample Nos. 7987-K, 12576-K, 15579-K, 20629-K, 21902-K, 21904-K, 27531-K, ~~28984-K~~ 28985-K, 31372-K, 31374-K, 40639-K, 40683-K, 40688-K, 40690-K.)

LIBELS FILED: Between June 3, 1948, and April 1, 1949, District of Utah, Western District of Missouri, Southern District of California, Northern District of Oklahoma, District of Kansas, Western District of Washington, Eastern District of Michigan, and Middle and Western Districts of Pennsylvania.

ALLEGED SHIPMENT: Between January 11, 1947, and February 15, 1949, by the Nue-Ovo Co., from Chicago, Ill., and by Research Laboratories, Inc., from Portland, Oreg.

PRODUCT: *Nue-Ovo*. 41 1-pint bottles; 147 units, each containing 3 1-pint bottles; and 8 cases, each containing 6 units of 3 1-pint bottles, at Salt Lake City and Ogden, Utah; Springfield, Mo.; Glendale and Vernon, Calif.; Miami, Okla.; Hutchinson and Lawrence, Kans.; Bellefonte and Pittsburgh, Pa.; Tacoma, Raymond, and Olympia, Wash.; and Detroit, Mich.